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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,404	08/05/2002	Michaela Arndt	4121-135	1053

7590 11/07/2006

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
10/049,404	ARNDT ET AL.	
Examiner	**Art Unit**	
Chun Crowder	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-6,15,19 and 22*.
   Claim(s) withdrawn from consideration: *7-14,16-18,20 and 21*.

PHILLIP GAMBEL, PH.D., J.D.
PRIMARY EXAMINER
TC 1600
11/2/06

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: for reasons of record. Applicant's arguments and the examiner's rebuttal regarding the rejections under 35 U.S.C. 112, first and second paragraphs, 102(b) and 103(a) are essentially the same of record. Applicant's arguments have been fully considered but have not been found persuasive.

1. Claim 22 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "more intense lysis". Applicant argues that the term is determined by comparing lysis between the claimed Fv antibody and the bimAbHRS-3/A9; thus is clear and definite. This is not found persuasive for reasons of record. The term "more intense lysis" is a relative phrase which renders the claim indefinite.

2. Claim 22 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant asserts that the antibody bimAbHRS-3/A9 (DSM ACC 2142) is the subject matter of the US Patent 5,643,759 in claim 1; thus it fullfills the deposit requriements under 35 U.S.C. 112, first paragraph and the deposited antibody is freely accessible from the DSM depository.

This is not found convincing for following reasons:

The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990). See MPEP 2404.01.

In addition, it is noted that the US Patent 5,643,759, for which applicant is relying on to satisfy all of the deposit requirement under 35 U.S.C. 112, first paragraph, has expired due to nonpayment of maintenance fees under 37 C.F.R. 1.362. Therefore, it is not clear if the antibody bimAbHRS-3/A9 (DSM ACC 2142) is readily available to the public or obtainable by a repeatable method under the conditions set forth in 37 CFR 1.801-1.809.

3. Claim 22 stands rejected under 35 U.S.C. 112, first paragraph for new matter regarding the limitation "CD30 carrying cells". Given the absence of rebuttal to the outstanding rejection of record in applicant's amendments, filed 10/24/2006; the rejection is maintained for reasons of record.

4. Claims 1-5, and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hartmann et al. (Blood. 1997, 89;6:2042-2047) (see entire document) for reasons of record.

Applicant argues that Hartmann et al. only teaches the genus of the Fv antibodies while the instant application is drawn to the species of Fv constructs having anti-CD16/CD30 specificities.

This is not found persuasive because Hartmann et al. clearly teach anti-CD16/CD30 bispecific antibody and the discussion of Hartmann et al. regarding the advantages of the Fv antibody is related to the use of the anti-CD16/CD30 bispecific antibody, thus, Hartmann et al. specifically teaches Fv antibody in the context of the use of the anti-CD16/CD30 antibody. Further, Hartmann et al. teach the use of the anti-CD16/CD30 bispecific antibody in treatment of refractory Hodgkin's disease (see entire document, particularly Abstract on page 2042).

Therefore, the teachings of Hartmann et al. anticipate the claimed invention.

5. Claims 1-6, 15 19, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hartmann et al (Leukemia and Lymphoma. 1998, 31:385-392. Reference AG on IDS) in view of Holliger et al. (PNAS. 1993, 93:6444-6448) for reasons of record and discussion above in Section 4.

6. Upon further consideration, as well as applicant's amendments and submission of the English translation of the foreign priority document Germany 199 37 264.0, the rejections under 35 U.S.C. 112, first paragraph regarding new matter issues of the limitation "inducing regression of Hodgkin's disease in vivo" and 35 U.S.C. 102(a) have been withdrawn.